

This package insert must be read carefully prior to use.

Total bilirubin assay kit for blood tests
(Classification No.: 30157001)

Clinimate BIL-2

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
4. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
5. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients

BIL-2 Acceleration Solution 1: Surfactant

BIL·D-BIL-2 Reactant Reagent 2:
Sodium nitrite

BIL·D-BIL-2 Dissolution Solution 2:
Sulfanyl hydrochloride

Intended Use

Measurement of total bilirubin in serum

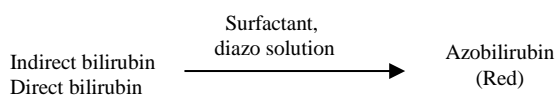
The total amount of serum bilirubin varies according to disintegration of hemoglobin and depending on the condition of metabolism in the liver. On the other hand, the direct to indirect bilirubin ratio plays an important role in the diagnosis and course evaluation of hepatobiliary disease.

Assay Principle

1. Assay Principle

When diazo reaction is allowed to the sample after adding a surfactant with an accelerating effect, all bilirubin react to form red azobilirubin.

The amount of total bilirubin is determined by measuring the absorbance of this red sample.



2. Features

- 1) Because the self-sample blank method is used, analytical results are hardly affected by

interfering substance.

- 2) Instrument will not be damaged because the acceleration solution contains surfactant.

Procedural Precautions *

1. Properties of Samples and Sampling Methods

- 1) Samples

Serum may be used.

- 2) Storage of samples¹⁾

If the isolated serum sample cannot be tested on the same day, specimens should be stored as follows:

2–10°C: for tests within 1 week

≤ -20°C: for tests after more than 1 week

Bring samples to room temperature (15–30°C) before use.

Bilirubin is isomerized by light irrespective of artificial or solar. Store this product under light shielding.

2. Interfering substances

Assay results are insensitive by hemoglobin (up to 500 mg/dL), ascorbic acid (50 mg/dL), or Intralipos (up to 2%).

3. Others

- 1) Always use Anaserum BIL Standard Solution for calibration.

- 2) Precautions for assay range

If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

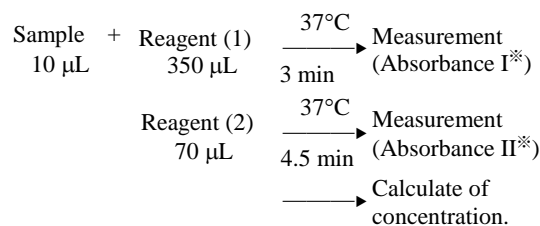
Reagent (1): BIL-2 Acceleration Solution 1 is ready to use.

Reagent (2): Dissolve BIL·D-BIL-2 Reactant Reagent 2 with BIL·D-BIL-2 Dissolution Solution 2.

After preparation, the reagent is stable for 7 days if stored, protected from light, at 2 to 10°C.

2. Assay Procedure

This product is compatible with various types of automated analyzers. An example of the assay procedure is indicated below.



^{*}Absorbance I and II: The difference in absorbance between 600 nm and 546 nm

Calibration material: Anaserum BIL standard (Manufacturer's assigned value)

Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range²⁾

0.2–1.1 mg/dL

- There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance

1. Sensitivity

- Reagent blank: absorbance being equal to or lower than 0.02
- Sensitivity: The absorbance is 0.19–0.26 per 10 mg/dL of bilirubin.

2. Accuracy: 90–110% of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation $\leq 3\%$

(Test methods used for 1. –3. are in-house methods.)

4. Measurement Range⁴⁾: (On Hitachi 7170S automated analyzer)

0.05–40.0 mg/dL

5. Correlation⁴⁾

Serum $N=55$ $r=0.997$ $y=0.94x-0.40$

Control method: Approved in vitro diagnostics (Alkaline azobilirubin method)

6. Standard Material

SRM916a (NIST)

Precautions for Use or Handling * *

1. Precautions for Handling (to Ensure Safety)

- All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
- BIL-2 Acceleration Solution 1 is highly acidic (pH 2.2–2.4) and BIL • D-BIL2 Dissolution Solution 2 contain hydrochloric acid. If the reagents accidentally come in contact with eyes or skin, take emergency measures immediately such as rinsing with water and get medical attention if necessary.

2. Precautions for use

- This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
- Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
- Do not replenish the reagents.
- Do not perform the assay under direct sunlight

3. Precautions for Disposal

- Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121°C for 20 minutes.
- To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as

sodium hypochlorite solution at a concentration of greater than 0.1%.

- The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
- The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life **

	Name	Storage temperature	Shelf life
Clinimate BIL-2	BIL-2 Acceleration Solution 1	Room temperature	1 year from the date of manufacture
	BIL • D-BIL-2 Reactant Reagent 2	2–10°C	2 years from the date of manufacture
	BIL • D-BIL-2 Dissolution Solution 2	Room temperature	2 years from the date of manufacture

(The expiration date is printed on the outer package.)

Packaging

	Name	Package
Clinimate BIL-2	(1) BIL-2 Acceleration Solution 1	4×100 mL
	(2) BIL • D-BIL-2 Reactant Reagent 2	4×for50 mL
	BIL • D-BIL-2 Dissolution Solution 2	4×50mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References *

- Sasaki M. et al.: Sampling of constituents of the human body, 79, Kodansha, 1972.
- Kitamura M. (author and editor): Practical Clinical Chemistry, 277, Ishiyaku Shuppan, 1974.
- Kanai I and Kanai M. (author and editor): Kanai's manual of clinical laboratory medicine. 32nd ed. 563, Kanehara Shuppan, 2005.
- In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer * *

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